

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
GREENVILLE DIVISION**

Jennifer Galloway,)	C/A No.: 6:17-cv-01076-MGL
)	
Plaintiff,)	
)	
vs.)	ANSWER OF DEFENDANTS
)	AUROBINDO PHARMA LIMITED,
Aurobindo Pharma Limited Inc. and)	INC. AND AUROBINDO PHARMA
Aurobindo Pharma U.S.A. Inc.,)	U.S.A., INC.
)	
Defendants.)	JURY TRIAL DEMANDED

TO: JOSEPH A. MOONEYHAM, ESQUIRE, ATTORNEY FOR PLAINTIFF:

Defendants Aurobindo Pharma Limited, Inc. and Aurobindo Pharma U.S.A., Inc. (hereafter referred to as “Aurobindo”) answers the Complaint of the Plaintiff herein as follows. Any allegations not hereinafter specifically admitted, denied or explained are deemed denied.

1. Aurobindo is without knowledge or information sufficient enough to form an answer as to the truth of the allegations in Paragraph 1.

2. Admitted.

3. Admitted.

4. Admitted.

5. Admitted.

6. Admitted.

7. Aurobindo is without knowledge or information sufficient enough to form an answer as to the truth of the allegations in Paragraph 7.

8. Aurobindo is without knowledge or information sufficient enough to form an answer as to the truth of the allegations in Paragraph 8.

9. Admitted.

10. Aurobindo denies the allegations in Paragraph 10.

11. Aurobindo admits the allegations contained in Paragraph 11.

12. Aurobindo admits that it has received final approval from the USDA to manufacture Sumatriptan.

13. Aurobindo denies the allegations in Paragraph 13.

14. In response to Paragraph 14, Aurobindo responds that this allegation constitutes a legal conclusion to which no response is required. To the extent the Court may deem a response is required, Aurobindo denies these allegations and demands strict proof thereof.

15. In response to Paragraph 15, Aurobindo responds that this allegation constitutes a legal conclusion to which no response is required. To the extent the Court may deem a response is required, Aurobindo denies these allegations and demands strict proof thereof.

16. In response to Paragraph 16, Aurobindo responds that this allegation constitutes a legal conclusion to which no response is required. To the extent the Court may deem a response is required, Aurobindo denies these allegations and demands strict proof thereof.

17. In response to Paragraph 17, Aurobindo responds that this allegation constitutes a legal conclusion to which no response is required. To the extent the Court may deem a response is required, Aurobindo denies these allegations and demands strict proof thereof.

18. In response to Paragraph 18, Aurobindo responds that this allegation constitutes a legal conclusion to which no response is required. To the extent the Court may deem a response is required, Aurobindo denies these allegations and demands strict proof thereof.

19. Aurobindo is without knowledge or information sufficient enough to form an answer as to the truth of the allegations in Paragraph 19.

20. Aurobindo is without knowledge or information sufficient enough to form an answer as to the truth of the allegations in Paragraph 20.

21. Aurobindo is without knowledge or information sufficient enough to form an answer as to the truth of the allegations in Paragraph 21.

22. Aurobindo is without knowledge or information sufficient enough to form an answer as to the truth of the allegations in Paragraph 22.

23. Aurobindo is without knowledge or information sufficient enough to form an answer as to the truth of the allegations in Paragraph 23.

24. Aurobindo is without knowledge or information sufficient enough to form an answer as to the truth of the allegations in Paragraph 24.

25. Aurobindo is without knowledge or information sufficient enough to form an answer as to the truth of the allegations in Paragraph 25.

26. Aurobindo is without knowledge or information sufficient enough to form an answer as to the truth of the allegations in Paragraph 26

27. Aurobindo is without knowledge or information sufficient enough to form an answer as to the truth of the allegations in Paragraph 27.

28. Aurobindo is without knowledge or information sufficient enough to form an answer as to the truth of the allegations in Paragraph 28.

29. Aurobindo is without knowledge or information sufficient enough to form an answer as to the truth of the allegations in Paragraph 29.

30. Aurobindo is without knowledge or information sufficient enough to form an answer as to the truth of the allegations in Paragraph 30.

31. Aurobindo is without knowledge or information sufficient enough to form an answer as to the truth of the allegations in Paragraph 31.

32. In response to Paragraph 32, Aurobindo incorporates by reference its responses to Paragraph 1 through 31 of Plaintiff's Complaint as fully and effectively as if set forth verbatim herein.

33. Admitted.

34. Aurobindo is without knowledge or information sufficient enough to form a belief as to the truth of the allegations in Paragraph 34.

35. Aurobindo denies the allegations in Paragraph 35.

36. Aurobindo denies the allegations in Paragraph 36.

37. Aurobindo denies the allegations in Paragraph 37.

38. Aurobindo denies the allegations in paragraph 38

39. Aurobindo denies the allegations in Paragraph 39.

40. Aurobindo denies the allegations in Paragraph 40.

41. Aurobindo denies the allegations in Paragraph 41.

42. Aurobindo denies the allegations in Paragraph 42.

43. In response to Paragraph 43, Aurobindo incorporates by reference its responses to Paragraph 1 through 42 of Plaintiff's Complaint as fully and effectively as if set forth verbatim herein.

44. Aurobindo denies the allegations in Paragraph 44.

45. In response to Paragraph 45, Aurobindo responds that this allegation constitutes a legal conclusion to which no response is required. To the extent the Court may deem a response is required, Aurobindo denies these allegations and demands strict proof thereof.

46. In response to Paragraph 46, Aurobindo responds that this allegation constitutes a legal conclusion to which no response is required. To the extent the Court may deem a response is required, Aurobindo denies these allegations and demands strict proof thereof.

47. Aurobindo denies the allegations in Paragraph 47.

48. Aurobindo denies the allegations in Paragraph 48.

49. Aurobindo denies the allegations in Paragraph 49.

50. Aurobindo denies the allegations in Paragraph 50.

51. In response to Paragraph 51, Aurobindo incorporates by reference its responses to Paragraph 1 through 50 of Plaintiff's Complaint as fully and effectively as if set forth verbatim herein.

52. Aurobindo submits that Paragraph 52 is directed toward a Defendant other than these Defendants, and, therefore, no response is required. To the extent the Court deems a response is required, Aurobindo is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 52 and, therefore, denies said allegations.

53. Aurobindo submits that Paragraph 53 is directed toward a Defendant other than these Defendants, and, therefore, no response is required. To the extent the Court deems a response is required, Aurobindo is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 53 and, therefore, denies said allegations.

54. Aurobindo submits that Paragraph 54 is directed toward a Defendant other than these Defendants, and, therefore, no response is required. To the extent the Court deems a response is required, Aurobindo is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 54 and, therefore, denies said allegations.

55. Aurobindo submits that Paragraph 55 is directed toward a Defendant other than these Defendants, and, therefore, no response is required. To the extent the Court deems a response is required, Aurobindo is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 55 and, therefore, denies said allegations.

56. Aurobindo submits that Paragraph 52 is directed toward a Defendant other than these Defendants, and, therefore, no response is required. To the extent the Court deems a response is required, Aurobindo is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 52 and, therefore, denies said allegations.

57. Aurobindo submits that Paragraph 57 is directed toward a Defendant other than these Defendants, and, therefore, no response is required. To the extent the Court deems a response is required, Aurobindo is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 57 and, therefore, denies said allegations.

58. In response to Paragraph 58, Aurobindo incorporates by reference its responses to Paragraph 1 through 57 of Plaintiff's Complaint as fully and effectively as if set forth verbatim herein.

59. Aurobindo denies the allegations in Paragraph 59.

60. Aurobindo denies the allegations in Paragraph 60.

61. Aurobindo denies the allegations in Paragraph 61.

62. Aurobindo denies the allegations in Paragraph 62.

63. Aurobindo denies the allegations in Paragraph 63.

64. Aurobindo denies the allegations in Paragraph 64.

65. In response to Paragraph 64, Aurobindo incorporates by reference its responses to Paragraph 1 through 63 of Plaintiff's Complaint as fully and effectively as if set forth verbatim herein.

66. In response to Paragraph 66, Aurobindo responds that this allegation constitutes a legal conclusion to which no response is required. To the extent the Court may deem a response is required, Aurobindo denies these allegations and demands strict proof thereof.

67. In response to Paragraph 67, Aurobindo responds that this allegation constitutes a legal conclusion to which no response is required. To the extent the Court may deem a response is required, Aurobindo denies these allegations and demands strict proof thereof.

68. Aurobindo denies the allegations in Paragraph 68.

69. Aurobindo denies the allegations in Paragraph 69.

70. Aurobindo denies the allegations in Paragraph 70.

71. Aurobindo denies the allegations in Paragraph 71.

72. In response to Paragraph 72, Aurobindo incorporates by reference its responses to Paragraph 1 through 71 of Plaintiff's Complaint as fully and effectively as if set forth verbatim herein.

73. Aurobindo denies the allegations in Paragraph 73.

74. Aurobindo denies the allegations in Paragraph 74.

75. Aurobindo denies the allegations in Paragraph 75.

76. Aurobindo denies the allegations in Paragraph 76.

77. Aurobindo denies the allegations in Paragraph 77.

78. Aurobindo denies the allegations in Paragraph 78.

79. Aurobindo denies the allegations in Paragraph 79.

80. Aurobindo denies the allegations in Paragraph 80.

81. In response to Paragraph 81, Aurobindo incorporates by reference its responses to Paragraph 1 through 80 of Plaintiff's Complaint as fully and effectively as if set forth verbatim herein.

82. Aurobindo denies the allegations in Paragraph 82.

83. Aurobindo denies the allegations in Paragraph 83.

84. Aurobindo denies the allegations in Paragraph 84.

85. Aurobindo denies the allegations in Paragraph 85.

86. Aurobindo denies the allegations in Paragraph 86.

87. Aurobindo denies the allegations in Paragraph 87.

88. Aurobindo denies the allegations in Paragraph 88.

89. Aurobindo denies the allegations in Paragraph 89.

90. Aurobindo denies the allegations in Paragraph 90.

91. Aurobindo denies the allegations in Paragraph 91.

92. Aurobindo denies the allegations in Paragraph 92.

93. Aurobindo denies the allegations in Paragraph 93.

94. Aurobindo denies the allegations in Paragraph 94.

95. Aurobindo denies the allegations in Paragraph 95.

96. Aurobindo denies the allegations in Paragraph 96.

97. Aurobindo denies the allegations in Paragraph 97.

98. Aurobindo denies the allegations in Paragraph 98.

99. Aurobindo denies the allegations in Paragraph 99.

FOR A FIRST DEFENSE

100. Plaintiff's Complaint fails to state facts upon which relief may be granted and, therefore, should be dismissed pursuant to Rule 12(b)(6) of the South Carolina Rules of Civil Procedure.

FOR A SECOND DEFENSE

101. Venue is inconvenient to the parties and this matter should be transferred to an appropriate jurisdiction.

FOR A THIRD DEFENSE

102. The doctrines contained in Restatement (Second) of Torts § 402A, A comment K, bar Plaintiff's claims against Aurobindo in whole or in part.

FOR A FOURTH DEFENSE

103. The doctrines contained in Restatement (Third) of Torts, Product Liability § § 4 and 6, bar Plaintiff's claims against Aurobindo in whole or in part.

FOR A FIFTH DEFENSE

104. Aurobindo alleges that any and all causes of action against it are barred by the applicable statutes of limitation and/or statutes of repose.

FOR A SIXTH DEFENSE

105. Aurobindo alleges that any damages sustained by the Plaintiff were due to and caused by the misuse or misapplication of the product described in the Complaint.

FOR A SEVENTH DEFENSE

106. The alleged injuries to Plaintiff was proximately causes by the misuse, abuse, alteration, and/or failure to properly utilize, maintain, or care for the product by persons other than Aurobindo.

FOR AN EIGHTH DEFENSE

107. Aurobindo alleges that the damages for which Plaintiff seeks recovery were due to and proximately caused by the voluntary actions taken in full knowledge of any associated risk, of which one, in the exercise of due care, should have known or appreciated, and, therefore, this voluntary assumption of risk is a complete bar to this action; or, in the alternative, a fact of comparative negligence.

FOR A NINTH DEFENSE

108. Any alleged negligent or culpable conduct of Aurobindo, none being admitted, was so insubstantial as to be insufficient to be a proximate or substantial contributing cause of Plaintiff's alleged injuries.

FOR A TENTH DEFENSE

109. The "learned intermediary" doctrine bars Plaintiff's claims

FOR AN ELEVENTH DEFENSE

112. Plaintiff's claims are barred, in whole or in part, because the product at issue was designed, manufactured, marketed and labeled with proper warnings, information, cautions, and instructions, in accordance with the state of the art and the state of scientific and technological knowledge.

FOR A TWELFTH DEFENSE

113. Plaintiff's claims are barred, in whole or in part, because the labels and information accompanying the products at issue were approved by the U.S. Food and Drug Administration or other appropriate regulatory agencies.

FOR A THIRTEENTH DEFENSE

114. Plaintiff's claims are barred, in whole or in part, because the product at issue was not defective or unreasonably dangerous in that it complied with, at all relevant times, all applicable government safety standards.

FOR A FOURTEENTH DEFENSE

115. Plaintiff's claims are pre-empted, in whole or in part, by applicable federal law relating to the design, testing, producing, manufacturing, labeling, distributing, modeling, processing, and supply of Sumatriptan.

FOR A FIFTEENTH DEFENSE

116. Plaintiff's claims are barred, in whole or in part, because Plaintiff's injuries, if any, were the result of conduct of Plaintiff, independent third parties, and/or events that were extraordinary under the circumstances, not foreseeable in the normal course of events, and/or independent, intervening and superseding causes of the alleged injuries, including but not limited to Plaintiff's pre-existing medical condition.

FOR A SIXTEENTH DEFENSE

117. If Plaintiff suffered injury or damages as alleged, which is denied, such injury or damage resulted from acts or omissions of persons or entities for which Aurobindo is neither liable nor responsible or resulted from diseases and/or causes that are not related to or connected with any product sold, distributed, or manufactured by Aurobindo. Such acts or omissions on the part of others or diseases or causes constitute an independent, intervening and sole proximate cause of Plaintiff's alleged injury or damages.

FOR A SEVENTEENTH DEFENSE

118. Plaintiff's claims are barred, in whole or in part, because Plaintiff's alleged injuries, if caused by Sumatriptan, which is denied, was the result of Plaintiff's own idiosyncratic reactions.

FOR AN EIGHTEENTH DEFENSE

119. Plaintiff failed to mitigate, which limits Plaintiff's damages, if any, in whole or in part.

FOR A NINETEENTH DEFENSE

120. Sumatriptan was fit and proper for its intended purpose and the social utility of the drug outweighed any possible risk inherent in the use of the product.

FOR A TWENTIETH DEFENSE

121. The claims of Plaintiff should be diminished in whole or in part in the amount paid to Plaintiff by any party or non-party with whom Plaintiff has settled or may settle.

FOR A TWENTY-FIRST DEFENSE

122. Plaintiff's claims are barred, reduced and/or limited pursuant to applicable statutory and common law regarding limitations of awards, caps on recovery, and setoffs.

FOR A TWENTY-SECOND DEFENSE

123. Aurobindo made no warranties of any kind, express or implied, or any representations of any nature whatsoever to Plaintiff. If any such warranties were made, whether express or implied, which Aurobindo specifically denies, then Plaintiff did not rely on any such representations or warranties and/or failed to give notice of any breach thereof.

FOR A TWENTY-THIRD DEFENSE

124. Notwithstanding the claims and contentions of Plaintiff, Plaintiff received all or substantially all of the benefit from the product that Plaintiff hoped and intended to receive, and, to that extent, any damages and/or restitution that Plaintiff might be entitled to recover from Aurobindo must be correspondingly reduced.

FOR A TWENTY-FOURTH DEFENSE

125. Plaintiff's causes of action are barred in whole or in part by Plaintiff's own contributory/comparative negligence.

FOR A TWENTY-FIFTH DEFENSE

126. Plaintiff's recovery, if any, shall be reduced by those payments that Plaintiff receives from collateral sources.

FOR A TWENTY-SIXTH DEFENSE

127. If Plaintiff has been injured or damaged, no injury or damages being admitted, such injuries were not caused by an Aurobindo product.

FOR A TWENTY-SEVENTH DEFENSE

128. Plaintiff's claim for punitive damages is barred because such an award would violate Aurobindo's due process, equal protection and/or other rights under the United States Constitution, the New Jersey Constitution, the South Carolina Constitution, and/or other applicable state constitutions.

FOR A TWENTY-EIGHTH DEFENSE

129. Plaintiff's claim for punitive damages is barred because Plaintiff has failed to allege conduct warranting imposition of punitive damages under New Jersey, South Carolina, and/or other applicable state laws.

FOR A TWENTY-NINETH DEFENSE

130. Plaintiff's claim for punitive damages is pre-empted, in whole or in part, by applicable federal law.

FOR A THIRTIETH DEFENSE

131. Plaintiff's claim for punitive damages is barred in whole or in part because Plaintiff is not entitled to compensatory damages, no fault or other admission being made.

FOR A THIRTY-FIRST DEFENSE

132. Plaintiff's fraud, misrepresentation, and suppression claims are re-empted in whole or in part. *See, e.g., Buckman Co. v. Plaintiffs' Legal Comm.* 531 U.S. 341, 343 (2001); *Penn. Employees Benefit Trust Fund v. Seneca Inc.*, 499 F.3d 239, 247 (3d Cir., 2007).

FOR A THIRTY-SECOND DEFENSE

133. Plaintiff's fraud, misrepresentation, and suppression claim is barred by Plaintiff's failure to plead them with reasonable particularity as required by Rule 9(b) of the Federal Rules of Civil Procedure.

FOR A THIRTY-THIRD DEFENSE

134. If any loss, damages, injury, harm, expense, diminution or deprivation alleged by Plaintiff was caused by Sumatriptan, which Aurobindo denies, Aurobindo is entitled to a reduction in any damages awarded which is attributable to Plaintiff's incurrent risk in continuing to use a product which, under the specific circumstances of said use, an ordinary person would have known was potentially causing health problems.

FOR A THIRTY-FOURTH DEFENSE

135. Plaintiff's causes of action are barred in whole or in part by Plaintiff's failure to assert a safer design for Sumatriptan.

FOR A THIRTY-FIFTH DEFENSE

136. With respect to Plaintiff's demand for punitive damages, Aurobindo specifically incorporates by reference any and all standards and limitations regarding the determination and enforceability of punitive damage awards set forth by the United States Supreme Court in the decision of *State Farm Mut. Auto Ins. Co. v. Campbell*, 123 S.Ct. 1513 (2003).

FOR A THIRTY-SIXTH DEFENSE

137. Aurobindo denies that it has been guilty of any conduct which warrants the issue or punitive damages being submitted to a jury.

FOR A THIRTY-SEVENTH DEFENSE

138. No punitive damages are warranted or allowable that would exceed comparable maximums established for criminal fines.

FOR A THIRTY-EIGHTH DEFENSE

139. To the extent Plaintiff seeks punitive damages against Defendants, Defendants denies such claim. An award of punitive damages under South Carolina law violates the Fifth, Sixth, and Fourteenth Amendments of the United States Constitution, and Article I, Section 3 of the South Carolina Constitution in that:

- a. The judiciary's ability to correct a punitive damage award only upon a finding of passion, prejudice or caprice is inconsistent with due process guarantees;
- b. Any award of punitive damages serving a compensatory function is inconsistent with due process guarantees;
- c. Any award of punitive damages based upon the wealth of the defendant violates due process guarantees;
- d. The juror's unfettered power to award punitive damages in any amount it chooses is wholly devoid of meaningful standards and is inconsistent with due process guarantees;
- e. Even if it could be argued that the standard governing the imposition of punitive damages exists, the standard is void for vagueness;
- f. Plaintiff's claims for punitive damages violates the equal protection clause of the Fourteenth Amendment of the United States Constitution, and Article I, Section 3 of the South Carolina Constitution in that the amount of punitive damages is based upon the wealth of the defendants; and
- g. Any award of punitive damages for conduct or activity of the defendants outside the State of South Carolina or otherwise directed to non-parties is inconsistent with the interest of federalism, and violates the governing authority of State Farm

Mut. Auto. Ins. Co. v. Campbell, 538 U.S. 408 (2003) and Phillip Morris USA v. Williams, 2007 WL 505781 (U.S. Sup. Ct. Feb. 20, 2007).

Furthermore, Plaintiff's claim for punitive damages violates the federal doctrine of separation of powers and Article I, Section 3 of the South Carolina Constitution for the reason that punitive damages are a creation of the judicial branch of government, which invades the province of the legislative branch of government. Defendants submit that like provisions of governing foreign law may likewise violate constitutional guarantees.

FOR A THIRTY-NINTH DEFENSE

140. The assessment of punitive damages in this action would violate the Commerce Clause of Article 1, Section 8 of the United States Constitution to the extent that such award punishes acts or omissions which have allegedly occurred solely outside of state boundaries.

FOR A FORTIETH DEFENSE

141. With respect to Plaintiff's demand for punitive damages, Aurobindo specifically incorporates by reference any and all standards or limitations regarding the determination and/or enforceability of punitive damage awards which arose in the decision of *BMW of N. America v. Gore*, 116 U.S. 1589 (1996).

FOR A FORTY-FIRST DEFENSE

142. Plaintiff's claim for breach of warranty is barred in whole or in part by the fact that Plaintiff's lacks privity with Aurobindo.

FOR A FORTY-SECOND DEFENSE

143. To the extent that South Carolina law applies to Plaintiff's claims, Plaintiff is limited and/or barred from recovery of punitive damages under strict liability or warranty-based claims. *See, e.g., Barnwell v. Barber-Colman Co.*, 301 S.C. 534, 537, 393 S.E.2d 162, 163 (1990); *Pinckney v. Orkin Exterminating Co.*, 268 S.C. 430, 432, 234 S.E.2d 654, 655 (1977).

FOR A FORTY-THIRD DEFENSE

144. To the extent that South Carolina law applies to Plaintiff's claims, damages are limited by S.C. Code Ann § 15-37-50, No liability or other admissions being made.

FOR A FORTY-FOURTH DEFENSE

145. Aurobindo hereby gives notice that it intends to rely upon such other defenses as may become available or apparent during the course of discovery and thus reserves its right to amend this Answer to assert such defenses.

WHEREFORE, Defendants Aurobindo Pharma Limited Inc., and Aurobindo Pharma U.S.A., Inc. demand just in its favor and against Plaintiff, dismissing Plaintiff's Complaint, with prejudice, together with costs and for such other and further relief as this Court may deem just and proper.

TURNER, PADGET, GRAHAM & LANEY, P.A.

April 25, 2017

By: s/ Bettis C. Rainsford, Jr.
J. Kenneth Carter, Jr. (Fed. I.D. No.5108)
R. Gerald Chambers (Fed I.D. No. 07025)
Bettis C. Rainsford, Jr. (Fed. I.D. No. 12372)
Post Office Box 1473
Columbia, SC 29202
kcarter@turnerpadget.com
gchambers@turnerpadget.com
brainsford@turnerpadget.com
Phone: (803) 254-2200
Fax: (803) 799-1459

**ATTORNEYS FOR DEFENDANTS
AUROBINDO PHARMA LIMITED, INC.
AND AUROBINDO U.S.A., INC.**